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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,091	12/02/2003	James W. McManus	21191	3427
210	7590	07/25/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			SACKY, EBENEZER O	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 07/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/726,091	Applicant(s) MCMANUS ET AL.	
	Examiner EBENEZER SACKY	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
4a) Of the above claim(s) 14-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/26/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is in response to applicant's election filed 05/01/06.

Status of the Claims

Claims 1-26 are pending.

Response to Restriction

Applicant's election with traverse of Group I, claims 1-13 in the reply filed on 05/01/06 is acknowledged. The traversal is on the ground(s) that instant Groups I-IV are all directed to the reductive alkylation of cyclic amines and all are concern with the production of alkylated cyclic amine products free of any borane complexes. This is not deemed persuasive because each of the various groups are patentably distinct as evidence by the various reactants and cyclic products obtained. Additionally, even though Groups I-IV are drawn to the production of cyclic amines, each of the Groups contain active steps and catalysts, which are unrelated and would be expected to raise differing issues of patentability. Moreover, each of the Groups can support their own patents, as each group is capable of being utilized alone.

Applicants next argue that there is no serious burden in searching the entire application because any reasonable search of Group I would include Groups II-IV. In response, there is nothing of record to support applicant's conclusionary statement and thus, the various Groups are considered patentably distinct. Therefore, claims 14-26 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

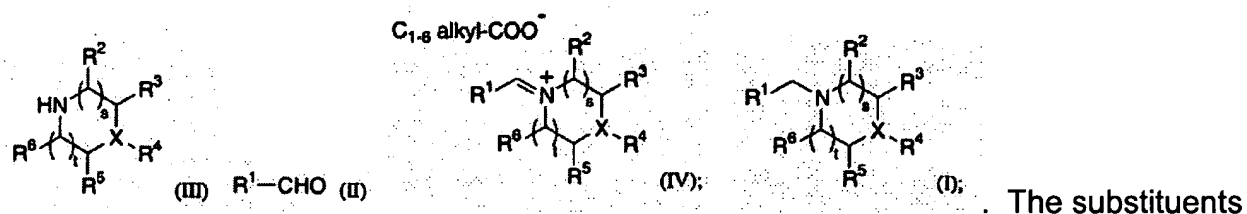
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Askin et al., (U.S. Patent number 5,508,404).

Applicants claim a process for preparing compounds of formula (I) (saturated cyclic amines), which comprises reacting an aldehyde of formula (II) with a cyclic amine of formula (III) in an organic solvent in the presence of a C₁₋₆alkylcarboxylic acid, to form a

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reaction mixture comprising an iminium salt of formula (IV), adding a tetrahydroborate salt to the reaction mixture to obtain a product comprising compound of formula (I) and borane complexes and treating the reaction mixture comprising compound of formula (I) with a catalyst selected from the group consisting of Pt oxide, Pt halide, Pd oxide and Pdhalide in the presence of an alcohol to cleave the borane complexes.



are as defined in claim 1.

Determination of the scope and content of the prior art (MPEP §2141.01)

Askin et al., teach the preparation of similar cyclic amines which comprises reacting an aldehyde compound such as 3-pyridine carboxaldehyde with an amine compound in the presence of suitable solvents such as isopropyl acetate, methanol, ethanol, isopropanol, ethyl acetate etc., in the presence of a variety of reducing agents, such as heterogeneous catalytic hydrogenation agents or reducing agents such as $NaBH(OAc)_3$ and formic acid. See the entire Patent, especially, columns 5 and 6 in each instance lines 1-65 and column 7, lines 1-41.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The process of Ashkin et al., differs from the instant process in that Ashkin et al., teaches a one-step process whereas the instant process requires two steps i.e., one-step vs. a multi-step process. However, performing the same process taught by the prior art, without the isolation of the intermediates is not held as a patentable distinction,

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but rather a conventional modification to one of ordinary skill in the art and thus, no ancillary teaching is required.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

Accordingly, at the time of filing this application, it would have been prima facie obvious to one of ordinary skill in the art to prepare N-containing substituted cyclic amine compounds as disclosed by Ashkin et al., guided by the disclosure with a reasonable expectation that the resulting product would be pure because Ashkin discloses that the process is amenable to a variety of solvents. See Example 25 of the reference. Hence, one in possession of Ashkin et al., guided by the disclosure is in possession of the instant process absent a showing of unexpected results or properties. The reaction that is being claimed is a predictable and expected reaction. Hence, a slight difference in process steps may serve to differentiate the instant process under U.S.C 102 but, does not serve to remove the relied upon reference under 35 U.S.C. 103. Thus, a multi-step process per say is un inventive.

Accordingly, the instantly claimed process would therefore have been suggested to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704.

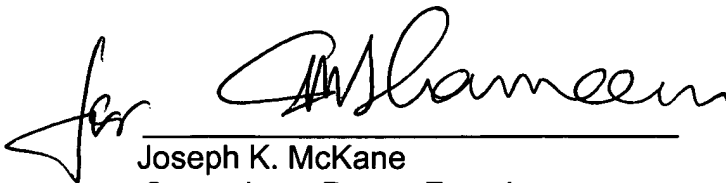
The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
July 17, 2006

A handwritten signature in black ink, appearing to read "for [unclear] McKane", written over a horizontal line.

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1